# CODE OF GOOD SCIENTIFIC PRACTICE

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## 1. INTRODUCTION

The Institute of Health Research Pere Virgili (IISPV) aims to promote, develop, manage and disseminate research and innovation in the field of life and health sciences in the Camp de Tarragona and the Terres de l'Ebre. Since 2008, it has been public in nature, with the entry of the Generalitat into the governing bodies, and is currently part of the CERCA program as an affiliated center.

The IISPV is constituted by: ICS Camp de Tarragona (University Hospital of Tarragona Joan XXIII), ICS Terres de l'Ebre (Hospital of Tortosa Virgen de la Cinta), University Hospital Sant Joan de Reus, Grup Pere Mata and the University Rovira I Virgili. The IISPV consists of more than 450 people, including responsible researchers and collaborators, training staff and research support technicians, which are distributed over 19 research groups. The activities of the research groups range from basic research to research in the field of primary and hospital care, as well as translational research typical of the biomedical field.

The IISPV's mission is to efficiently manage its own and other people's resources and provide the best service available to Health professionals, through the promotion, consolidation and translation of research in the biosanitary field to improve the health and well-being of the population (preferably) of Camp de Tarragona and Terres de l'Ebre.

The public entrusts the scientific community with the responsibility for undertaking high quality scientific research. Along with this responsibility comes the expectation that this research work is always done in good faith, with honesty and integrity. The Code of Good Scientific Practice of Pere Virgili Research Institute (IISPV) represents a set of recommendations and commitments governing scientific activities. The aim is to create an environment conducive to high-quality research and prevent problems from arising in relation to the integrity of scientists in their work. The recommendations complement current legal regulations.

This document has been prepared and agreed by the Board of Directors of the Institute.

## 2. GENERAL PRINCIPLES OF THE RESEARCH

### 2.1. Exercise of methodical doubt

The principle of scientific knowledge is the ability to question the why of facts. Science seeks objective knowledge that can be assumed to be true in a particular socio-cultural context. To achieve this, it follows a reflective process in two stages: the methodical doubt and the validation of an explanatory hypothesis. The methodical doubt implies independence of the judgment and the non-acceptance of any idea as absolute or definitive. To validate a hypothesis, one must find evidence or arguments that consolidate it. This questioning attitude at the forefront of scientific work must always be accompanied by researchers.

### 2.2. General rules governing scientific practice

- Observation and experimentation in basic and clinical practice, in the laboratory or in the natural environment, are aimed at obtaining data that facilitate the answers to a priori asked scientific questions. Research must follow well-defined and rigorously designed working protocols that can be replicated, examined, evaluated and understood by any other researcher. The design must be careful in order to optimize the use of resources, always taking into account the work rules of the center in which the research is carried out.
- We must maintain systematic skepticism and openness to doubt, even in the face of our own results. One of the main tests for validating a scientific finding is its reproducibility. The more amazing or desired the result, the more important it is to reproduce it within the research group, before communicating it externally.
- It is necessary to always be vigilant of any form of expectation motivated by self-interest or prejudice of any kind. Critical sense must be maintained in order to promote a systematic alertness that can detect misinterpretation as a result of limitations in experimental design, excessive generalization, and superficiality in interpretation.
- It is essential to make a systematic, controlled and safe collection of primary data, and to guarantee the storage of the documentation generated during the term established by the type of study. The data must be clear and understandable, and include the methods used to generate it.

### 2.3. Application to the IISPV

- IISPV staff is committed to building on this Code, also considering the laws and regulations listed in other documents (see Annex I. Legislation, rules and documents) and making it known to all of its staff.

- Researchers will be free to determine methods to solve problems, provided that they respect the recognized ethical principles and practices, and accept limitations that arise from the circumstances of the research or for operational reasons.
- IISPV staff must provide funding agencies with guarantees that the resources allocated to research are used as efficiently as possible, in compliance with ethical postulates.
- Before the scientific community, the dissemination of results, including negative ones, must be ensured to avoid unnecessary duplication.
- Scientific malpractice, both in the conduct of the research process and in its dissemination to the scientific community, must be prevented.
- The means must be used to ensure that the resources allocated to research are best utilized, as well as the protection of the rights of clinical study participants.

## 3. RESEARCH IN HEALTH SCIENCES

- Clinical care and health care are based on a set of scientific knowledge, technical skills and attitudes of the professionals in the area. This knowledge is reached through systematic research and its transmission is carried out through scientific publications and teaching.
- Research carried out in the basic, clinical or public health fields, allows renewing, updating and increasing existing knowledge through an orderly procedure. This is a chain of processes aimed at the ultimate purpose, such as the improvement of professional exercise and public health.
- Quality research allows professionals to keep their knowledge up to date, and an open attitude to change, which results in an improvement in care. To achieve this, it is necessary to sum the available resources, such as the effort, time and dedication of the research staff.
- A particularly relevant aspect is that when efforts are directed at a particular project and direction, other options are ruled out, and thus the importance of deciding in the proper sense should be emphasized.
- Communicating the results allows the transmission of knowledge and scientific progress. It is therefore essential once it is in the public domain to avoid duplication, improvement in procedures and the development of new technology from which the whole society benefits.
- In order for the whole process to be accepted by the society that provides the useful resources for its development, a set of ethical postulates is required to be fulfilled and specific conditions are required. The scientific community values and dictates the validity of new knowledge.

- The research environment is competitive in terms of obtaining resources and funding. These resources may come from outside funding agencies, nonprofits, for-profit companies, or the healthcare system itself. The search for funding sources should not underestimate the moral requirement behind the process.
- Research is currently being carried out in ever broader fields. Multicenter studies are becoming more common. The center and the research staff must commit themselves, on one hand, to a careful review of participation in this type of study and, on the other, not to participate in it until this study has been carried out.
- The Guide to Best Practices in Research at the IISPV is a commitment of the institution and the research staff regarding the completion of any scientific process, with the highest possible level of quality.

## 4. PLANNING OF A RESEARCH PROJECT

In order for it to be successful, a research project requires planning and structurization. Without these elements, a project cannot be considered and cannot be registered as such in research bodies, as it lacks the elements of guarantee and protection referred to in this document.

### 4.1. Project design phase

1) Appointment of the principal researcher.
2) Review of pre-existing information.
3) Formulation of the hypotheses and objectives.
4) Select the type and design of the study.
5) Estimating the sample size, if applicable.
6) Definition of a data analysis plan and statistical analysis techniques.
7) Determine the minimum resources needed to make the project viable. Set a budget.
8) Definition of the system of data collection and custody.
9) Planning tasks.

There are several specific guidelines for each type of design that help in its development and facilitate implementation, evaluation and subsequent publication[1].

[1] https://implementationscience.biomedcentral.com/track/pdf/10.1186/s13012-019-0897-z

### 4.2. Development of a protocol

1) Compulsory preparation.
2) Minimum contents.
3) Research team.
4) Publication rights and economic agreements.

### 4.3. Approval of a protocol

1) Collaboration agreements between services.
2) Scientific approval.
3) Ethical approval.
4) Legal approval.
5) Commitment of the research team.
6) Existence of a contract, if applicable.

### 4.4. Economic conditions

In the event of an economic consideration, there must be an economic agreement. This agreement will be written and the conditions agreed between the parties will be collected. It will be signed by the promoter, the legal manager of the IISPV, the principal investigator and the health care institution in which the study is conducted. The economic management of the funds obtained will be channeled through the IISPV and all its recommendations will be followed. In the event that a project is not managed directly through the IISPV, as a result of alliances or agreements with other institutions, the IISPV must become aware of it, as if it were a project of its own.

## 5. RESEARCH INVOLVING HUMAN SUBJECTS

All research protocols involving the direct participation of human subjects or based on any form of information or biological samples obtained from such subjects must always have received, as a minimum requirement, approval from the corresponding clinical research ethics committee. When research involves patients, members of the research team who are not responsible for treating the study participants must collaborate and not interfere with any decisions made by the physician responsible for treatment.

### 5.1 Prior informed consent document

Research projects involving patients or volunteers must give their informed consent with their signature or that of their legal representative before starting.

### 5.2 Ethical principles

The biomedical research carried out at the center must be based on the universally recognized ethical principles of autonomy and the principle of benefit. The principle of autonomy must be especially respected by disabled people, to whom their tutors respond.

### 5.3 Pre-informed consent information

The information that must be provided to the patient participating in a project must be prior to signing of the acceptance document. This information should be given in the best way possible for the participant, respecting the cultural values of each person. Patients must have the time they need to consult the proposal and make a sound decision.

### 5.4 Written information

Patients must be provided with a document stating the potential benefits and risks of participating in the study, the first and last name of the person reporting them, and the main researcher. It must indicate their explicit acceptance, or that of their tutors.

### 5.5 Economic compensation

If the project contemplates financial compensation for the participants, whether these are patients or healthy volunteers, it must be stated, as well as the relation to the extraordinary expenses that their participation may entail.

### 5.6 Approval of the CEIm

Unless the IISPV Ethical Committee for Clinical Research (CEIm) has evaluated and approved the protocol, the research cannot be started. This committee ensures that the rights of patients, healthy volunteers, and people involved in a research project are respected. The mandatory reports must be sent to this committee on an annual basis and at the closing of the study. A/e: ceim@iispv.cat

### 5.7 Notification and action in case of possible adverse effects

If adverse effects occur, the promoter must be notified immediately. If these are potentially serious, the patient should be removed from the study.

### 5.8 Biobank

All collections of human samples for research purposes must be registered in the National Biobank Registry of the Carlos III Health Institute[2]. The Biobank of the IISPV is responsible for processing the register of all the collections of the institution in the National Register. The biobank complies with current legal regulations.

In order to register the collections you can contact the coordination of Biobanc (biobanc@iispv.cat).

## 6. RESEARCH INVOLVING EXPERIMENTAL ANIMALS

Animal research must be governed by the principle of 3 errors ("replace, reduce and refine"), and every aspect must always be justified.

### 6.1 Justification of the animal model

The need to use animals as experimentation subjects should always be argued, indicating the absence or contraindication of alternative methods that can replace them.

### 6.2 Determination of the number of animals

The sample size of the study should be determined, and it should be reduced as much as possible.

### 6.3 Reduction of suffering

Procedures should be specified to prevent the suffering of animals, as well as the method of slaughter, which should be as appropriate as possible, according to the principle of refinement.

### 6.4 Approval of the Ethical Committee for Animal Experimentation

The research cannot be started until it has been definitively approved by the Animal Experimental Ethics Committee. At the end of the study, annual and final mandatory reports must be submitted to the ethics committee.

[2] https://www.isciii.es/QueHacemos/Servicios/BIOBANCOS/BiobancoNacionalISCIII/Paginas/InformacionGeneral.aspx

## 7. SAFETY, HEALTH AND ENVIRONMENT

Researchers must know the safety, health and environmental protection measures that must be taken into account when carrying out research activities.

Each center will ensure that the research is carried out ensuring the safety and health of the personnel involved, as well as respect for the environment. Research groups must ensure that their activities are carried out within the framework of policies for the prevention of occupational risks and environmental protection, both those of the center and those established by current legal regulations, which includes specific sections for genetically modified organisms (see Annex I. Legislation, regulations and documents).

## 8. MAKING PROJECTS

### 8.1 Responsibility of the principal researcher

The lead researcher is the person responsible for the project. If this person is replaced, it must be authorized by the funding agency and the management of the center, before proceeding with the research project. In these circumstances, the proposed person must have at least the same capacity as the substituted person.

### 8.2 Supervision of the study

The lead researcher must make sure that his/her research team follows the approved protocol, including careful monitoring of predoctoral research staff and other staff in the training process, to ensure that they receive and comply with the protocol.

### 8.3 Modifications

If significant changes are needed to the project, they must always be formalized in writing. If they are really relevant, authorization will be required from all those agencies that approved their implementation in the first place.

### 8.4 Audits

The principal investigator must collaborate in the inspection visits and checks that both the center and the relevant external agency decide to make, as well as in the preparation of the necessary progress reports, according to the planned periodicity.

### 8.5 Record of expenses

The research team is responsible for the efficient use of the budget allocated to the project. A transparent and detailed economic management of the payments and their vouchers will be carried out. These should enable accurate reporting and review by funding agencies.

### 8.6 Use of equipment

Researchers are required to keep the research material in the best possible condition and to adhere closely to the rules of operation. Relevant periodic calibrations should be performed, both to ensure the validity and accuracy of the results and to ensure the physical safety of the people using them.

The equipment purchased by the researcher is of preferential use but not exclusive to that person. The researcher must provide access to the rest of the Institution's research staff and allow them to make use of the equipment, provided that it complies with the specific regulations of the care facilities and there is no prejudice to the main purpose for which itwas acquired. All equipment incorporated by the institution through research projects becomes part of its heritage and will be included in its inventory. The Institution must be responsible for its maintenance and ensure its proper functioning.

### 8.4 Registration, documentation, storage, custody and sharing of the data and biological or chemical material resulting from the searches

#### *A. Data collection and conservation plan*

Every research protocol must provide for a data collection system, and the record of the biological or chemical material resulting from the research, as well as a plan for its safekeeping, conservation and eventual rejection and destruction, in accordance with current law.

#### *B. Record of data and rectifications*

The principal investigator, as well as the collaborating staff, shall collect all data from the experiments and observations from his research line without exception. This information must be permanently registered in databases, registration books, or in any other format, under conditions that allow it to be reviewed by third parties. Records should also include changes, errors, negative, unexpected, or discordant results, as well as the name of the person responsible.

### *C. Conservation of the data and samples collected*

The necessary means and infrastructures must be provided in order to guarantee the correct custody and preservation of the documentation and biological or chemical material resulting from the research. Also, if there is an electronic record, a specific backup plan and physical location must be included.

### *D. Custody and access to data*

All people who are part of the research team must have access to the information of the data obtained and its interpretation. The person responsible for the research must have a unique register of the different elements of data collection (notebooks, databases, etc.) and custody of samples. Access to this information must be available in the event that third parties request it.

### *E. Ownership of data and samples*

All the primary documentation (data collection books, databases, etc.) and the biological or chemical material obtained during the course of a research project are the property of the institution or institutions to which the person responsible for the project is linked. In the case of holders of a place linked to a healthcare center or university, the ownership belongs to the two institutions.

The person responsible for the project must be responsible for the registration, correct storage and safekeeping of the data. In the case of a change of Institution, this person must, whenever necessary, provide a copy of part or all of the registration books to the person who succeeds them, as well as the existing electronic information and data collection books or aliquots of available biological or chemical material. When the change affects the person responsible for the research, this process must be carried out under the responsibility and supervision of the management of the center.

### *F. Sharing of data and samples with third parties*

The data and the material resulting from a search will be public and will be able to be shared by third parties, with the exception of cases in which restrictions have been established arising from their possible commercialization.

The assignment will require the prior request by the applicant. It must indicate the intended use, as well as a statement stating who assumes the possible expenses that may be incurred. The person in charge of the group must always be informed of these events. The request will be subject to the transfer protocol and the final approval of the group that generated the data.

The assignment may be limited for reasons of availability, competitiveness or confidentiality. Material and personal data must be shared, but not identifiable. Otherwise, the donors will need to sign a specific consent permitting the transfer.

***G. Time of storage of data and samples***

All original information, as well as biological or chemical material stored as a result of any research line, must be stored for a minimum of 10 years from the first publication of results, except in cases where the law allows shorter periods or demands longer ones. If permitted by the institution, information and material may be stored for longer periods. Its final destination will always require the approval of the person in charge of the research. In the case of clinical trials, the shelf life is at least 15 years. Experimental projects can reduce the custody period to 5 years.

### 8.5 Disposal of waste

The leftover items of the research must be stored and disposed of according to their danger and risk, following the existing rules for the conservation of the environment and the protection of the people.

### 8.6 Intelectual Property Rights

The law states that research data and samples belong to the institution and not to researchers. In the event that a researcher (whether or not a member of the team) terminates his relationship with the center, he only has the right to have the data obtained directly. If you are the principal researcher, you must have the approval and supervision of the center to use this data outside the institution.

The intellectual property of the data that is the result of a research project is the property of the institution that hires the person, but may be subject to agreements that surrogate it to third parties (for example, from the IISPV to related institutes) or to the promoter).

### 8.7 Protection of personal data

At all times the confidentiality of the clinical, biological and genetic data, as well as the samples belonging to the patients, must be guaranteed. The transfer of personal data to other institutions or bodies must be done in such a way that the identity of the person cannot be revealed, in accordance with the regulations established by Organic Law 15/99, of December 13, and General Regulation of Data Protection (RGPD) 2016/679, of April 27, 2016 on protection of personal data (see Annex 3 "Legislation, regulations and documents").

### 8.8 Intellectual property to third parties

In the case of a clinical trial, the information provided to a study promoter body cannot be disseminated by any means and must be reliably stored. The agreements stipulating the rights to be contemplated during and as a result of the research must be established in writing.

### 8.9 Final report

At the end of each project, a final report must be made, which must, at a minimum, include: the identification of the principal investigator and other people involved, the identification of the laboratory where the study was carried out, the circumstances that may have affected it, the start and end dates of the research, its results and any possible modifications to the protocol.

The final report will be sent to the Scientific Directorate of the Institute, who will review it and file it with the rest of the project documents.

## 9. COMMUNICATION, DISSEMINATION AND RESULTS TRANSFER

### 9.1. Obligation to disseminate and/or transfer results

Without the dissemination and/or transfer of the results, the research process remains incomplete. The results must be communicated to the scientific community, whatever their outcome, even if they do not match the predicted data. This encourages scientific debate, prevents repetition of experiments, and allows for the development of new hypotheses.

The lead researcher has the duty to make his findings public, and he is the only person who can authorize their publication.

### 9.2. Authorship of scientific works, publications and patents

Information related to the authorship of scientific papers, publications and patents:

The status of each author does not depend on the profession or hierarchical position, nor on the nature of the established employment relationship, but rather on the contribution to the research. In order to be an author in a publication or patent, it is necessary:

1) To have contributed substantially to its creative process, both in its conception and design or during execution, as well as in the analysis and interpretation of the derived data.
2) To have contributed to the preparation of the resulting communications, reports or publications.
3) Ability to present their personal contribution and discuss the main aspects of the research.
4) Authors must accept in writing the final wording of the original manuscripts that are processed for registration or publication.

Provision of data, opinions or subjects of experimentation.

Participation in resource collection or data collection, such as the provision of routine data or the provision of experimentation subjects, does not necessarily justify authorship, but must be recognized in the acknowledgments section.

For those projects that plan to use samples, analyses or opinions made by third parties, it is advisable to establish a communication and authorship plan in advance, which must take into account the intellectual contribution and any other aspect related to copyright .

**Partially responsible authors**

When there is an author in a publication who cannot assume responsibility for all the content, his or her specific contribution must be identified, except in cases where this issue is already regulated by editorial standards.

**Honorary and ghost authorship**

The person linked to the research group who, due to their hierarchical position or employment relationship, claiming to be an ex officio author, violates academic and research freedom, hereby commits an act of injustice and can be considered an abuse of authority. The omission of anyone who has contributed (according to the criteria set out in section 8), constitutes an act of misappropriation and infringement of the intellectual property of the other authors.

**Indication of authorship in reports**

The publication of reports, work reports or technical documents, or any other writing addressed to third parties, must always include the relationship between the authors, the center (or centers) involved, and the grants received, in the same terms as in a scientific publication or patent.

**Order of authorship**

As a general rule, the signature order of the authors involved in scientific publications should be as follows:

The first person who appears as the author is the one who made the most effort during the research, the one who performed the experiment or the fieldwork, and prepared the first draft of the article.

The latter is the senior person, responsible for the management, to whom the ultimate responsibility for the experimental design and the research result is addressed. He is usually responsible for the development and oversight of the research program within the framework of the project.

The rest of the authors may appear in order of importance and, as the case may be, in alphabetical order. The correspondent author is primarily responsible for the entire editorial process, as well as for any interactions resulting from the publication (you can consult the document: IISPV Affiliation and Acknowledgments Policy.

**Shared main authorship**

Scientific publications have the right to justify the order in which the authors sign. When two or more authors have dedicated the same work and shared the main work during the preparation of the manuscript, they must be considered both as first authors. This circumstance will be explicit in the publication of the original. The same criterion may also apply to intermediate and senior authors.

### 9.3. Curriculum vitae should be signed

In the preparation of a personal Curriculum vitae, the author is responsible for the accuracy of its content. Consequently, it is advisable that such a document should be signed by the individual who presents it. In the case of a group CV, it is sufficient for the document to be signed by the individual responsible for presenting it.

### 9.4. Acknowledgments

The purpose of the acknowledgments is to acknowledge the help of the organisms and the people involved in the research. In order to be able to mention them, they must have given their prior consent.

### 9.5. Ethical Publications

The publications cannot be redundant. They cannot be arbitrarily fragmented to increase their number. All data obtained must be provided accurately. If any case or variable is eliminated, the change must be justified.

### 9.6. Presentation in the mass media

Only after the publication or communication of research results in a scientific journal, or an equivalent review system, it can be released to media experts. Before you require the formal consent of the institution (comunicacio@iispv.cat) and the agency that has funded the project, if necessary. If this is a coordinated project, it is necessary to have the approval of all the participants and entities. Sensationalist formats that may create false expectations should be avoided.

## 10. CONFLICT OF INTEREST

### 10.1 Concept and origin

There is a potential conflict of interest when the principal investigator, or any component of his team, has been influenced by (1) undeclared economic compensation and/or (2) a personal interest, other than scientific, in the design, the realization, or communication of the results of a research project.

### 10.2 Notification

Depending on the case, any conflicts of interest should be reported to the funding agencies, the staff who evaluate and certify the experimental validity of the project, or to the editors of scientific journals at the time of the evaluation of the study and the consequent decision-making concerning its disclosure.

## 11. RESEARCH STAFF

The IISPV has a Professional Research Career that is annexed to this document and describes the following positions:

- Principal researcher
- Postdoctoral researcher
- Predoctoral researcher

## 12. RESERACH INTEGRITY COMMITTEE

### 12.1. Research Integrity Committee (CIR)

The CIR is a body set up freely and voluntarily by the members of the Internal Scientific Committee, aimed at promoting knowledge and adapting the best practice guide. Likewise, the CIR arbitrates queries and conflicts that may arise, and assists the research mediator when necessary.

The CIR acts independently and is at the service of the research staff of the centers adhering to the fulfillment of this document of best practices, with the sole purpose of supporting the quality of research and helping to preserve its integrity.

The functions of the CIR are:

a. Ensure compliance with the precepts included in this document.

b. To act as an arbitral institution in the face of uncertainties or conflicts that may arise in relation to the integrity of the research, once the mediator's actions have been exhausted. In that sense, the decisions of the Committee are binding on anyone subject to conflicts.

c. Inform and sensitize the scientific community on events, needs and guidelines regarding the ethical and deontological aspects of biomedical research.

d. Be alert and receptive to issues related to research integrity.

Field of activity:

In relation to the above functions, the CIR must at all times guarantee the diligence, independence and impartiality in its actions, as well as the anonymity and confidentiality in the treatment of personal data, and the soundness of the information generated. It must guarantee objectivity, motivate deliberations and ensure the fairness of its decisions, as well as the possibility of its appeal. Communications with the CIR should be sent to the following email: cir@iispv.cat

### 12.2. Ombudsperson

Must be a person nominated by the management of the Institute, on the proposal of the Internal Scientific Committee, to act as a mediator in case of conflict regarding good scientific practices. This person must exercise discretion regarding information that

indicates a possible malpractice and is not obliged to disclose any information to the Institute's management bodies.

The Ombudsperson and the CIR are required to defend and protect the complainant and to avoid the negative consequences that his accusation may lead to. This is particularly important if the complainant belongs to the same group as the defendant.

The Board of Directors will appoint, together with the Director, the most appropriate research mediator (Ombudsperson) to act as a mediator in each situation that arises.

## 13. MISCONDUCT IN RESEARCH

According to the most widely established definition, misconduct is the invention, falsification and/or plagiarism of data, or other actions that deviate from the practices commonly accepted by the scientific community regarding the proposal, execution and/or presentation of the research results. Any errors or deficiencies in good faith in the interpretation of the data are not included.

To prevent the occurrence of situations of scientific malpractice, knowledge of the principles of scientific ethics must be encouraged, ensuring that there is expert and frequent supervision and monitoring at all levels; avoid excessive pressure for results and promote information exchange between the groups. The Institution must implement the rules of good practice in research included in this document, with a particular emphasis on data collection systems. Not only do these rules reduce the risk of mistakes, they also greatly facilitate the identification of cases of scientific misconduct.

## ANNEX I: LEGISLATION, REGULATIONS & DOCUMENTS

### A: Research involving human subjects

Declaration of NurnBerg, Standing Committee of European Doctors, CPME). Nuremberg, 1967.

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. The National Comission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.

Royal Decree Act 426/1980, on February 22, for which the Law 30/1979, on October 27, on Organ Extraction and Transplantation was developed (BOE, núm. 63, 13-03-1980, p. 5705).

Drug Law 25/1990, December 20, (BOE, núm. 306, 22-12-1990, p. 38228).

European Standard. Clinical Investigation of Medical Devices for Human Subjects. EN 540: 1993. June 1993.

Convention for the Protection of Human Rights and Human Dignity with Respect to the Applications of Biology and Medicine (Convention on Human Rights and Biomedicine). Approved by the Committee of Ministers of the European Council on November 19, 1996. Opened for the signature of the States in Oviedo, on April 4, 1997 and ratified by the Spanish Parliament on October 5, 1999 (BOE, no. 251, 10-20-1999, p. 36825).

Universal Declaration on the Human Genome and Human Rights: From Principles to Practice. UNESCO, February 3, 2000.

Circular 15/2001 of the Spanish Medicines Agency for the application of Royal Decree 561/1993, of April 16, on the conduct of clinical trials with medicines.

Law 29/2006, of July 26, on guarantees and rational use of medicines and health products. (BOE, No. 178, 2007-07-27, p. 28122).

Decree 406/2006, of October 24, regulating the requirements and the accreditation procedure of the clinical research ethics committees. (DOGC, No. 4748, October 26, 2006, pp. 44904).

Helsinki Declaration of the World Medical Association. Ethical principles for medical research in humans. Helsinki, Finland, June 1964. Revised by the General Assembly, October 2013.

Regulation 536/2014 of the European Parliament and of the Council, of April 16, 2014, on clinical trials of medicines for human use, and repealing Directive 2001/20 / EC (DOUE L, no. 158, 27 -05-2014)

Royal Decree 1090/2015, of December 4, regulating clinical trials with medicines, the Ethics Committees of drug research and the Spanish Register of Clinical Studies. (BOE, No. 307, 12-12-2015, p. 121923).

**Biobanks**

Royal Decree 1716/2011, of November 18, which establishes the basic requirements for authorization and operation of biobanks for the purposes of biomedical research and treatment of biological samples of human origin, and regulates the operation and organization of the National Registry of Biobanks for Biomedical Research. (BOE, No. 290, 2-12-2011, p. 128434).

Decree 234/2013, of October 15, for which the authority is authorized by the constitution and the operation of the biobanks with means of biomedical research in Catalonia and the Catalan Biobank of Biobancs. (DOGC, No. 6482, 10-17-2013).

**B: Animal Research**

Decree 214/1997, of July 30, which regulates the utilization of animals for experimentation and for high scientific finalities. (DOGC, No. 2450, 08-07-1997)

Royal Decree 65/2006, of January 30, which establishes requirements for the import and export of biological samples. (BOE, No. 32, 7-02-2006, p. 4626).

Law 32/2007, of November 7, for the care of animals in their exploitation, transport, experimentation and slaughter (BOE, No. 268, 8-11-2007, p. 45914).

Royal Decree 53/2013, of February 1, which establishes the applicable basic rules for the protection of animals used in experimentation and other scientific purposes, including teaching. (BOE, No. 34, 8-02-2013, p. 11370).

**C: Protection of workers**

Law 31/1995, of November 8, on the prevention of occupational risks. (BOE, No. 269, 10-11-1995, p. 32590).

Royal Decree 665/1997, of May 12, on the protection of workers against the risks related to exposure to carcinogens at work. (BOE, No. 124, 05-24-1997, p. 16100).

Royal Decree 664/1997, of May 12, on the protection of workers against risks related to exposure to biological agents at work and the Technical Guide for the evaluation and prevention of risks related to exposure to biological agents. (BOE, No. 124, 05-24-1997, p. 16111).

Law 54/2003, of December 12, reforming the regulatory framework for the prevention of occupational risks. (BOE, No. 298, 12-13-2003, p. 44408).

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